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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/029,408

12/26/2001

Larry Caldwell

CALD-005

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/029,408	<b>Applicant(s)</b> CALDWELL ET AL.	
	<b>Examiner</b> SIMON J. OH	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 24-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 24-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, all received on 14 November 2007.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-3, 5-8, 10-12, 14-18, 29 and 34 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) is maintained.

The rejection of Claims 4, 9 and 13 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Hirano *et al.* (U.S. Patent No. 5,869,087) is maintained.

The rejection of Claim 19 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Shudo *et al.* (U.S. Patent Application Publication No. 2002/0176886) is maintained.

The rejection of Claim 20, 21 and 23 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Shudo *et al.* (U.S. Patent Application Publication No. 2002/0176886) is rendered moot with the cancellation of those claims.

The rejection of Claim 22 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Hirano *et al.* (U.S. Patent No. 5,869,087) and Shudo *et al.* (U.S. Patent Application Publication No. 2002/0176886) is rendered moot with the cancellation of that claim.

The rejection of Claims 24-28 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Hirano *et al.* (U.S. Patent No. 5,869,087), and a bandage is maintained.

The rejection of Claims 30-33 under 35 U.S.C. 103(a) over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Liebschutz (PCT Publication WO 02/22109 A2) is maintained.

Claims 35, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

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The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

As one of ordinary skill in the art would be aware of the symptoms of carpal tunnel syndrome, it would be reasonable to expect that successful treatment of this condition would include the amelioration of symptoms such as tingling, numbness, and pain. Therefore, such limitation drawn to the amelioration of such symptoms is considered to be implicitly met by the teachings of the prior art. Additionally, it is expected that successful treatment of carpal tunnel syndrome would conclude with cessation of such symptoms for an extended period of time, particularly as the claims are drawn to methods of treatment that are open in scope and may therefore include other methods of treatment beyond those that are explicitly recited. Therefore,

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such claim limitations drawn to the length of the amelioration of such symptoms are also implicitly met by the prior art. Thus, the instantly claimed invention is *prima facie* obvious.

Claim 37 and 40 is rejected under 35 U.S.C. 103(a) being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Liebschutz (PCT Publication WO 02/22109 A2).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the use of a topical NSAID formulation containing about 0.5% to 2% by weight of an active NSAID agent, nor does it disclose a topical NSAID formulation where the NSAID is the only active agent.

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The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Liebschutz *et al.* reference discloses a patch containing diclofenac (See Abstract). The diclofenac may be present in the form of diclofenac epolamine in an amount that is preferably from 1% to 5% of the matrix layer (See Page 3, Section (b)(1)).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

It would be obvious to one of ordinary skill in the art to combine the Bockow patent with the Liebschutz *et al.* reference, as one would be motivated to use the patch disclosed in Liebschutz *et al.* for its disclosed advantages of good adhesion without irritation and improved bioavailability (See Page 2, first paragraph). As the Bockow and Liebschutz *et al.* reference are both drawn to topical formulations for the treatment of pain, the references are analogous and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

***Response to Arguments***

Applicant's arguments filed 14 November 2007 have been considered but are not considered to be persuasive. The applicant has argued that the prior art does not make the instantly claimed invention obvious on the rationale that

1) Carpal tunnel syndrome (CTS) and musculoskeletal disorders have entirely different pathologies;

2) Because these two conditions arise from entirely distinct pathologies, those of ordinary skill in the art generally treat them differently; and

3) There are anatomical reasons why one of ordinary skill in the art would not predict success in the claimed methods without actually performing the methods and obtaining positive results.

The applicant also alleges that the prior art is not applicable against the claims because Bockow teaches the treatment of musculoskeletal disorders with an omega fatty acid spirulina formulation and that Edwards only provides exemplification with banana peel extract compositions.

However, in determining what is taught by the prior art, the examiner draws broader conclusions. Specifically, that Bockow teaches that the application of analgesics and anti-inflammatory agents is useful for the treatment of CTS. Secondly, even though differences do exist between neuropathies and musculoskeletal disorders, where CTS is particularly concerned, it has not been shown where the re-characterization of CTS from a musculoskeletal disorder to an entrapment neuropathy has led to a complete abandonment of prior art methods that were successful in treating CTS. Even though this re-characterization has led to a greater



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understanding of CTS from a pathological perspective, it does not seem that prior art methods of treatment such as the topical application of analgesics are now of no value. Those prior art methods include immobilization, surgery, physical therapy, and improvement in ergonomics, all of which have served to varying degrees of amelioration of CTS symptoms.

The examiner also appreciates the physiological difficulties in the local administration of active agents to the carpal tunnel. However, the examiner cannot ignore the teachings of the prior art that have disclosed such local administration of anti-inflammatory or analgesic agents for the treatment of CTS near the loci of pain. It is presumed to be a valid and properly enabled teaching and it will be applied against the instant claims as such.

The examiner's rationale in combining the prior art against the claims is that:

- 1) The prior art teaches the methods for the topical administration of anti-inflammatory and/or analgesic agents for the treatment of CTS
- 2) The prior art also teaches that such administration should take place on or near the loci of pain; and
- 3) Other topical preparations of anti-inflammatory and/or analgesic agents, including patches, can be used in the above methods with a reasonable expectation of success.

Again, the examiner does recognize that there is now a newer and better understanding of the pathology of CTS. However, that alone is not sufficient to show that prior art methods of treating CTS are now without any value. Therefore, the prior art remains properly applicable against the instant claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIMON J. OH whose telephone number is (571)272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh  
Examiner  
Art Unit 1618

sjø

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618